K113622

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
(21 CFR 807.92)
for ***ORION™ II CT CVC***

MAY 18 2012

SUBMITTER:
Health Line International Corporation
803 N. 1250 W. – STE 1
Centerville, Utah 84014

ESTABLISHMENT REGISTRATION NUMBER:
3006097687

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DATE PREPARED:
November 30, 2011

NAME OF MEDICAL DEVICE:

Proprietary Name:	***ORION™ II CT CVC***
Regulation Name:	Intravascular Catheter
Common/Usual Name:	Central Venous Catheter (CVC), single, double and triple lumen

DEVICE CLASSIFICATION:

Classification Panel:	General Hospital
Regulatory Class:	Class II
Product Code:	FOZ
Regulation Number:	21 CFR 880.5200

PREDICATE DEVICE:

Proprietary Name:	***SYNERGY™ CT PICC (K101329)***
Regulation Name:	Percutaneous, Implanted, Long-term Intravascular Catheter
Common/Usual Name:	Catheter, Intravascular, Therapeutic, Long Term
Classification Panel:	General Hospital
Regulatory Class:	Class II
Product Code:	LJS
Regulation Number:	21 CFR 880.5970

DEVICE DESCRIPTION:

The *ORION™ II CT CVC* is a family of central venous catheters designed to perform infusion, intravenous therapy, blood sampling and also power injection of contrast media studies. The catheters, made of radiopaque polyurethane tubing, are inserted in a central vein. Each *ORION™ II CT CVC* has a kink resistant, gradual tapered catheter design. The *ORION™ II CT CVC* kit includes a catheter and introduction components. The catheter is supplied sterile and non-pyrogenic in a variety of kit configurations.

The *ORION™ II CT CVC* is indicated for dwell times shorter than 30 days. The *ORION™ II CT CVC* catheter assemblies have been tested to withstand power injection of worst-case viscosity injection media at 5 ml/sec with a maximum power injector pressure of 300 psi.

The *ORION™ II CT CVC* product line has catheters in 16 G and 14 G single lumen, 5 Fr and 7 Fr dual lumen and 7 Fr triple lumen. Catheters range from approximately 13-30 cm long. The catheters are attached to an injection-molded polyurethane hub that has extension legs with Luer lock fittings for access attachment. All ORION™ II CT CVC products have a maximum recommended infusion rating is 5 ml/sec. The maximum pressure or pounds per square inch (psi) of the power injector utilized should not exceed 300 psi.

INTENDED USE:

The *ORION™ II CT CVC* is intended to be used by medical professionals for short-term access to the central venous system for infusion, intravenous therapy, blood sampling and for power injection of contrast media. All *ORION™ II CT CVC* products have a maximum recommended infusion rating of 5 ml/sec.

INDICATIONS FOR USE:

The *ORION™ II CT CVC* is indicated for short term (less than 30 days) access to the central venous system for intravenous administration of fluids, medications, blood products, and/or nutritional therapy solutions when prescribed. Blood sampling and power injection of contrast media may also be conducted with the *ORION™ II CT CVC*.

TECHNOLOGICAL COMPARISON TO PREDICATE DEVICES:

New device is compared to Marketed Device? Yes. It is compared to a legally marketed predicate.

Does the new device have the same indication statements? Yes, with the exception of the insertion site and the removal of the long term access indication. Additionally, the *ORION™ II CT CVC* indications contain solutions detail for the CVC device.

Do the differences alter the intended therapeutic/diagnostic/etc. effect (i.e. deciding may consider impact on safety and effectiveness)? No.

Does the new device have the same technological characteristics, e.g. design, material, etc.? Yes. The CVC device of this submission, the *ORION™ II CT CVC*, is identical to that of (K101329), *SYNERGY™ CT PICC*, with the exception of the length. In fact, the *ORION™ II CT CVC and the SYNERGY™ CT PICC* are manufactured by the same company, Health Line International Corporation, the submitter of this submission. The basic fundamental scientific technology of the device has not changed. There may be minor variations in the contents of the introduction kit components.

Could the new characteristics affect safety or effectiveness? No.

Do the new characteristics raise new types of safety and effectiveness questions? No. There are no new types of safety and effectiveness questions.

Do accepted scientific methods exist for assessing effects of the new characteristics? Yes.

The FDA's *Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters,* dated 3/16/95 was used to determine the appropriate methods for evaluating the device's performance.

Sterilization requirements of ISO 11135-1:2007, *Sterilization of Health Care Products – Ethylene Oxide – Part 1: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices.*

Biocompatibility requirements according to of ISO-10993, *Biological Evaluation of Medical Devices Part 1: Evaluation and Testing*. Test profiles for externally communicating, blood-contacting, prolonged contact devices will be met.

These and other standards were used to determine the appropriate methods for evaluating the device's performance.

Are performance data available to assess effects of new characteristics? Yes. Verification testing was performed according to protocols based on the above-referenced guidance document recommendations and additional standards.

Do performance data demonstrate equivalence? Yes. Performance data gathered in design verification testing demonstrated that the ***ORION™ II CT CVC*** is substantially equivalent to the noted predicate device.

CONCLUSION

The ***ORION™ II CT CVC*** met all established acceptance criteria for performance testing and design verification testing. This testing demonstrated that the ***ORION™ II CT CVC*** is safe and effective for its intended use, and based on FDA's decision tree is substantially equivalent to the following predicate device: *SYNERGY™ CT PICC (K101329).*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Nola Benstog
QA/RA Director
Health Line International Corporation
803 North 1250 West, Suite 1
Centerville, Utah 84014

MAY 18 2012

Re: K113622
Trade/Device Name: ORION™ II CT CVC
Regulation Number: 21 CFR 880.5200
Regulation Name: Catheter, Intravascular, Therapeutic, Short Term
Regulatory Class: Class II
Product Code: FOZ
Dated: April 24, 2012
Received: April 25, 2012

Dear Ms. Benstog:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): _____

Device Name: ***ORION™ II CT CVC***

Indications For Use:

The ORION™ II CT CVC is indicated for short term (less than 30 days) access to the central venous system for intravenous administration of fluids, medications, blood products, and/or nutritional therapy solutions when prescribed. Blood sampling and power injection of contrast media may also be conducted with the ORION™ II CT CVC.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

5/17/12

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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